REMARKS

Claims 1, 2, 5, 7-12, and 44-53 are pending in this application. Claims 3-4, 6, and 13-43 were previously cancelled. Claims 1, 7, 51, and 52 are currently amended.

Claim Amendments

Applicants respectfully submit that no new matter is introduced into the application by way of the instant claim amendments.

Support for the recitation "wherein the polymer is resistant to biological degradation" is found, for example, in the specification on page 4, line 31, which states that '[t]he polymer is resistant to biological degradation and is not permeable through biological membranes" and on page 4, line 34 to page 5, line 3, which states that '[t]he polyacrylamide hydrogel is . . . resistant to enzymatic and microbiological degradation."

Support for the recitation "wherein the polymer is not water-soluble" is found, for example, on page 5, line 2 of the '670 specification, which states that "[f]urthermore, the polymer is not water-soluble."

Support for the recitation "from 2 to 60 Pas" is found, for example, on page 5, line 35 to page 6, line 2, which states that "[i]n a suitable embodiment, the hydrogel is characterized in that it has complex viscosity from about **2** to 90, such as from 5 to 80 Pas, preferably from about 6 to **60**, 6 to 40, 6 to 20, such as 6 to 15 Pas." (emphasis added). Further support is found on page 9, lines 5-9, which states that "[t]he hydrogel according to the present invention preferably has a complex viscosity from about **2** to 90, such as 5 to 80 Pas, typically from about 6 to 76, such as from about 6 to **60**, 6 to 40, 6 to 20, such as 6 to 15 Pas. (emphasis added).

Statement of Substance

Applicants respectfully thank Examiner Miller for the courtesy of granting a telephonic interview on in this application with the undersigned and Pierre Kary, representative of the Applicant company. During this interview both prior art rejections were both discussed but the focus of this interview was a clarification of the Purkait reference and why this reference does not teach or suggest a stable hydrogel as claimed which is useful as an endoprosthetic material.

It was explained that Purkait instead relates to a composite gel which is not biostable and which in fact has "good elimination" properties.

Moreover, it was explained that while this composite gel is described as "biocompatible", that this is not consistent with a biostable hydrogel possessing the properties claimed herein. Rather, it was emphasized that this term is defined by Purkait in paragraph [20], lines 57-68 as "the material is either excreted from the body or is easily metabolized into harmless byproducts. Non-metabolized materials must be sufficiently small that they can be transported through the membranes and excreted by the body in the urine or fecal matter." Accordingly it was argued that the hydrogel of Purkait is not biostable and in fact possesses very different viscosity properties than the subject hydrogel and therefore can not itself function as an endoprosthetic [unlike the biostable polymeric hydrogel of the present invention].

It was further noted during the interview that technical information and potentially an Affidavit would be submitted supportive of these arguments, i.e., that the hydrogel of Purkait does not possess the complex viscosity of the hydrogel of the present invention.

Rejections

35 U.S.C. § 103(a)

Claims 1-2, 5, 7-12, 45, and 48-53 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Annis.[1] In addition, claims 1-2, 5, 7-12, 44-46, and 48-53 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Purkait.[2]

Applicants respectfully disagree and traverse these rejections. Without acquiescing in the merits of the rejection, Applicants have amended independent claims 1, 51, and 52 to include the recitations that the polymer is resistant to biological degradation and is not water-soluble. Accordingly, these recitations are now present in all pending claims, which are collectively addressed by the arguments here.

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1 Annis et al. Urinary incontinence prosthesis. EP 0 248 544.

2 Purkait, B. Filling material for soft tissue implant prostheses and implants made therewith. EP 0 895 785.

- **Annis**

Applicants respectfully assert that Annis does not teach or suggest—by itself or in combination with any other prior art references—the claimed hydrogels in the instant application. Based on the following lines of evidence, the prosthetic devices disclosed in Annis neither have nor suggest the viscosity characteristics required by the claims of the instant application.

First, applicants have submitted a declaration under 37 C.F.R. § 1.132 by Robert Lessél, an expert in polymer chemistry. (**Exhibit A**). While noting that "Annis does not explicitly define the viscosity of the polymer hydrogel," the declaration also indicates that "the person skilled in the art, based upon a reading of Annis as a whole, would immediately recognize that the Annis material would generally be outside the claimed values for complex viscosity." Lessél Declaration, ¶ 10. Among the most pertinent observations in this declaration are the following;

> Annis describes a material which is "sized and formed" (column 2, line 16), typically into a "kidney shaped" (column 3, lines 38-39) with defined (and more importantly, definable) dimensions. It is immediately evident to the skilled person that the Annis material has a much higher viscosity (and likely elasticity) than the values defined for the hydrogel of the present invention. Lessél Declaration, ¶ 11.
>
> Annis describes (column 2, lines 23-26) that the material should have the same physical properties as "natural tissues". As a person skilled in the art, based upon my understanding and my experience in working with polymeric materials intended for use inside a human or animal body, this inherently describes the Annis material as having a viscosity typically in the range of 95-900 Pas. It must be noted however that some forms of animal tissue may have a viscosity as low as 90 Pas, perhaps even 85 Pas. Lessél Declaration, ¶ 12.
>
> A homogenized polymer hydrogel having a complex viscosity of 2 to 60 Pas is fluid-like. It possesses non-Newtonian fluid characteristic (hence the descriptor "complex viscosity" rather than "viscosity"). Temporarily disregarding the not entirely academic distinction between "complex viscosity" and "viscosity", I will comment upon the complex viscosity feature of the claimed invention. Homogenized non-Newtonian fluids having a complex viscosity of 2 to 60 Pas cannot support their own weight over an extended period of time. Without the constraints of a container or frame, such as material collapses under its own weight into a formless mass. Such materials cannot be defined in terms of its shape. This is in contradistinction to the material defined by Annis which is

> formed and shaped and maintains its shape. Lessél Declaration, ¶ 13.
>
> A more detailed reading of Annis further allows the skilled person that the material by Annis would have physical properties that could allow sutures to secure the material. In contradistinction, the polymer hydrogel of the present invention, with the defined complex viscosity, would immediately be understood by the person skilled in the art not to be suitable for sutures since it would not be resistant enough to hold a suture. To illustrate the inappropriateness in layman terms, it would be like trying to sew Vaseline or mayonnaise to Jell-O that wasn't ready yet. Lessél Declaration, ¶ 14.

Based on this analysis, Dr. Lessél concludes that "the complex viscosity values of the polymer hydrogel of the present invention are well below what would be inherently understood by the teaching of Annis." Lessél Declaration, ¶ 14.

Second, applicants have submitted two technical publications to convey a general sense of the scale and range of viscosity values for a spectrum of materials. **Exhibit B** provides an excerpt from A Practical Approach to Rheology and Rhometry by Gebhard Schramm. Section 2.4 (Pg. 9) of this excerpt is entitled "Dynamic viscosity" and shows that materials falling within the 2 to 60 Pas range include honey (10 Pas) and some polymer melts (which can range from 1-100 Pas). Similarly, **Exhibit C** discloses that materials falling within the 2 to 60 Pas range include molasses (10.8 Pas), ink (45 Pas), and ketchup (50 Pas).[3]

The shapeless form of these materials contrast with the shaped form of the prosthetic device in Annis. Applicants emphasize, however that the viscosity values reported in Exhibits B and C cannot be compared directly (and in a 1:1 empirical manner) to the polymers of the present invention because the claimed hydrogels are non-Newtonian fluids definable by complex viscosity rather than viscosity. Nevertheless, these observations are consistent with the conclusion that the viscosity of the hydrogels disclosed in Annis is significantly outside the viscosity range of the hydrogels claimed in the instant application.

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[3] This document reports viscosity in centiPoise units, which are interchangeable with milliPascal units, i.e. 1000 cP = 1000 mPa = 1 Pa.

- **Purkait**

Applicants further submit that Purkait does not teach or suggest—by itself or in combination with any other prior art references—the claimed hydrogels in the instant application. In particular, the composite gel-based filling materials disclosed in Purkait neither have nor suggest at least two characteristics of the claimed hydrogels.

First, the polymers comprising the filling material in Purakit are highly susceptible to biological degradation—and meant to be so. For example, Purkait teaches that "particularly advantageous characteristics" of the filling materials include the property that "the material is either excreted from the body or is easily metabolized into harmless byproducts." That is, "[n]on-metabolized materials must be sufficiently small that they can be transported through membranes and excreted by the body in the urine or fecal matter."[4]

In contrast, the polymers claimed in the instant application are resistant to biological degradation, including "enzymatic and microbiological degradation." Applicants respectfully submit that examiner's final office action, mailed on April 30, 2008, overlooks this crucial difference from the polymers in Purakit by asserting that "Purkait's hydrogel is within an envelope, this is considered stable." Not only does this assertion fail to recognize the distinct characteristics of the polymers in the two cases, but it also ignores the fundamental difference between the inventions: The present application relates to a hydrogel used **as** an endoprosthesis itself, while Purkait relates to a (different) hydrogel used as a filling material in an endoprosthesis.

The expert declaration by Robert Lessél set forth this position:

> As to whether the Purkait composite hydrogel is biostable, it is readily understood by the person skilled in the art that Purkait composite hydrogel serves as a filling material for an endoprosthesis rather than as an endoprosthesis itself. This is a fundamental difference between the materials: Purkait describes a filling material which is intended to be

[4] Purkait, ¶ [0020].

> biologically unstable in the undesired even of having contact with human tissue whereas the present invention describes a material which is stable when in contact with human tissue. This stability allows it to function as an endoprosthesis; moreover, a permanent endoprosthesis. Lessél Declaration, ¶ 7.
>
> Purkait repeatedly states that the material is to be encapsulated in an envelope and that leakage is an unwanted scenario. In the event of leakage from the silicone envelope, the composite material is to be eliminated. In order to be eliminated, the material must be degraded. Accordingly, the person skilled in the art understands Purkait to describe a polymer composite which is substantially biologically degraded. Lessél Declaration, ¶ 8.
>
> From our reading of Purkait, a 2% component of the substantially biologically unstable composite hydrogel of Purkait may be biologically stable. When reading Purkait, the person skilled in the art understands that the residual 2% material is undesirable. The person skilled in the art learns from Purkait that biological stability is not desirable. In contradistinction, the claims of the present invention describe a polymer which, in its entirety, would be permanent and biologically stable when in contact with the human body. Lessél Declaration, ¶ 8.

Second, whereas the claimed polymers in the instant application are water-insoluble, the polymers comprising the filling material in Purkait are nearly—if not completely—water soluble. The expert declaration by Robert Lessél provides the following insights:

> [W]ith respect as to whether the hydrogel of Purkait is water soluble, the person skilled in the art immediately understands from Purkait teaches that all or almost all of the composite hydrogel is non-crosslinked polyacrylamide. The person skilled in the art knows that non-cross linked polyacrylamide is water soluble. Purkait accordingly describes a composite hydrogel material wherein the major component is very water soluble, as understood by the person skilled in the art. In Purkait, a minor component may or may not be water insoluble. In contradistinction, the present invention relates to a product, as understood by the person skilled in the art merely by the components of the polymerization process, which is not, in whole or in part, water soluble. Lessél Declaration, ¶ 4.
>
> Irrespective of whether the insolubility is specified in the claim, based upon a teaching in the claim to polymerize acrylamide in the presence of methylene-bis-acrylamide, the person skilled in the art, would generally understand the resultant product to be as a whole water insoluble, particularly at the defined molar ratios of the components. Purkait teaches of a composite hydrogel which is substantially water soluble with a possible minor component in the composite hydrogel which may or may not be water insoluble. Lessél Declaration, ¶ 5.

Based on this analysis, the declaration concludes that "the person skilled in the art understands Purkait to describe a polymer composite which is substantially water soluble in contradistinction to the present invention which teaches, (and apparently now specifies) a polymer that is not water soluble." Lessél Declaration, ¶ 6.

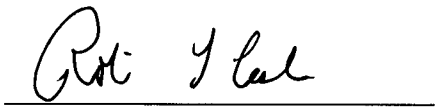
In light of the instant amendments and remarks provided herein, Applicants respectfully request reconsideration and withdrawal of the rejection of 1-2, 5, 7-12, 44-46, and 48-53 under 35 U.S.C. § 103(a).

CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: October 30, 2008 By: 

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